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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,134	09/14/2006	Irina Velikyan	PH0334	7198
36335	7590	11/18/2010	EXAMINER	
GE HEALTHCARE, INC.			PERREIRA, MELISSA JEAN	
IP DEPARTMENT 101 CARNEGIE CENTER			ART UNIT	PAPER NUMBER
PRINCETON, NJ 08540-6231			1618	
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			11/18/2010	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/552,134	VELIKYAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	MELISSA PERREIRA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 October 2010.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-3,5 and 8-16 is/are pending in the application.
  - 4a) Of the above claim(s) 16 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3,5 and 8-15 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>6/30/10</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____ .

## DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/28/10 has been entered.

### ***Claims and Previous Rejections Status***

2. Claims 1-3,5 and 8-16 are pending in the application. Claim 16 is withdrawn from consideration.
3. The rejection of claims 1-3,5 and 8-15 under 35 U.S.C. 103(a) as being unpatentable over Griffiths et al. (WO03/059397) in view of Yngve (Int. Diss. Abs. **2001**, 62), Bottcher et al. (US 5,439,863) and Lidström et al. (*Tetrahedron* **2001**, 57, 9225-9283) and in further view of Maier-Borst et al. (GB 2056471A) and Wheaton et al. (*Industrial and Engineering Chemistry* **1951**, 43, 1088-1093) is maintained.
4. The rejection of claims 1-3,5 and 8-15 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,2 and 6-14 of copending Application No. 10/522,206 is maintained.
5. The rejection of claims 1-3,5,8-13 and 15 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3,7-15 of copending Application No. 11/358,681 is maintained.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-3,5 and 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffiths et al. (WO03/059397) in view of Yngve (Int. Diss. Abs. 2001, 62), Bottcher et al. (US 5,439,863) and Lidström et al. (*Tetrahedron* 2001, 57, 9225-9283) and in further view of Maier-Borst et al. (GB 2056471A) and Wheaton et al. (*Industrial and Engineering Chemistry* 1951, 43, 1088-1093).

8. Griffiths et al. (WO03/059397) discloses a radiolabeling method for the preparation of a NOTA or DOTA (containing N hard donor atoms) labeled  $^{68}\text{Ga}$  for use in PET (p18, paragraph 1) and the development of a  $^{68}\text{Ge}/^{68}\text{Ga}$  in-house titanium dioxide generator (p7, paragraph 3; p8). The macrocyclic-chelating agent, such as DOTA may be linked to a peptide that can target the site of a disease, thus generating a bifunctional chelating agent comprising a targeting vector which will be site-specific (p9, paragraph 1).

9. The method of producing a radiolabeled gallium complex involves reacting the solution of a peptide labeled macrocyclic chelate with the  $^{68}\text{Ga}$  diluted from the  $^{68}\text{Ge}/^{68}\text{Ga}$  titanium dioxide generator which can be fitted with an anion-exchange membrane, such as a Q5F cartridge (p12, paragraph 1; p13, paragraph 2; p16, paragraph 2). Griffiths et al. teaches that the advantage of the gallium-68 generator of

the disclosure is that gallium-68 is eluted without unwanted over-dilution (p16, first full paragraph) where the prior art teaches of gallium-68 eluted from previous generators is present in extremely dilute solution, typically under one picomole per milliCurie (p4, paragraph 3). Griffiths et al. (WO03/059397) does not disclose a <sup>68</sup>Ga-DOTA-oligonucleotide, the synthesis of the <sup>68</sup>Ga-DOTA-peptide complex via microwave, or the anion exchanger comprising HCO<sub>3</sub><sup>-</sup> counterions of the instant claims.

10. Yngve (Int. Diss. Abs. 2001, 62) discloses the preparation of a phosphorothiolated <sup>68</sup>Ga-DOTA-oligonucleotide and a <sup>68</sup>Ga-DOTA-octreotide for use in PET (p12, paragraph 2; p21, last paragraph; p40, paragraph 2). The production of <sup>68</sup>Ga is from a generator system via an ion-exchange column (p39, paragraph 3). The labeling of octreotide (a synthetic octapeptide that show high selectivity for the somatostatin receptor) has been widely investigated due to the role of somatostatin for tumor diagnosis and treatment. Radiolabeled octreotides are routinely used for clinical applications.

11. Bottcher et al. (US 5,439,863) discloses the preparation of metal complex salts via microwave irradiation (column 3, lines 38-50, especially line 45). The complexes are prepared from metal ions and multoothed chelating ligands that occupy more than one coordination site on the central metal atom (column 3, lines 55+; column 4, lines 44-51). The ligands of the disclosure may include those with dioxime (N and O containing), etc. groups (column 5, lines 20-31). The use of microwave as the high-energy input allows for a single-stage reaction with short reaction time (i.e. a few minutes) and without

costly purification steps (column 2, lines 25-34; column 3, lines 38-50; column 4, lines 17-21; column 5, lines 56+, especially lines 65+).

12. Lidström et al. (*Tetrahedron* **2001**, 57, 9225-9283) discloses that microwave technology has been used since the late 1970s for inorganic chemistry and 1980s for organic synthesis. The shorter reaction times are the main advantage of the microwave technique as microwave heating can be very rapid, producing heat profiles not easily accessible by other heating techniques (p9226, paragraph 2; p9231, third full paragraph). The microwave technique can provide 100 W (figure 10).

13. Maier-Borst et al. (GB 2056471A) discloses the separation of <sup>68</sup>Ga from its parent nuclide with water via passing the eluate from a generator column into an anion exchanger comprising quaternary ammonium groups incorporated in a matrix of styrene and divinylbenzene and washing the anion exchanger with water (p4, lines 44-48).

14. Wheaton et al. (*Industrial and Engineering Chemistry* **1951**, 43, 1088-1093) discloses strongly basic anion exchange resins which are quaternary ammonium salts having a polystyrene crosslinked with divinylbenzene base (Dowex 1 and 2) (p1088, paragraph 1). Dowex 1 and 2 are provided in various forms, such as bicarbonate (tables I and II). Wheaton et al. teaches that the bicarbonate form of the Dowex 2 is shown to have increased stability for several days, even at higher temperatures (e.g. 95°C) and minimal swelling (4%) wherein the anion form of the Dowex with the maximum swelling is 13%. The bicarbonate form of the Dowex 2 is one of a finite number of anionic forms of the Dowex 2 wherein the less preferred embodiment (bicarbonate) is similar and/or equivalent to the preferred embodiment/standard

(chloride) as Wheaton et al. states that the volume changes of Dowex 2 in different salt concentrations and in different ionic forms are not large, which is an added advantage of this resin (p1089, Resin Swelling; Figure 3).

15. At the time of the invention it would have been obvious to one ordinarily skilled in the art to use the  $^{68}\text{Ga}$  from a  $^{68}\text{Ge}/^{68}\text{Ga}$  titanium dioxide generator as disclosed by Griffiths et al. to produce a  $^{68}\text{Ga}$ -DOTA-oligonucleotide complex, such as that of Yngve for use as a PET tracer as Griffiths et al. teaches that the titanium dioxide generator produces gallium-68 that is more concentrated (i.e. nanomolar, micromolar) than one picomole per milliCurie of the prior art. Also, Griffiths et al. teaches of the conjugation of  $^{68}\text{Ga}$ -DOTA to peptides and therefore, it is obvious to those skilled in the art to make known substitutions on compounds that are similar in structure and function, such as the oligonucleotides of Yngve for the peptides of Griffiths et al. to observe the effects on the function of such compounds and to use the observations/data to further manipulate a compound to generate the desired effect, such as sites-specific targeting of the complexes to somatostatin for tumor diagnosis and treatment.

16. The microwave synthesis technique for the method of producing metal-chelate complexes was known by Bottcher et al. at the time of the invention. Therefore, it would have been obvious to one skilled in the art to utilize the microwave acceleration technique for a faster and more reproducible preparation of the  $^{68}\text{Ga}$ -DOTA-oligonucleotide complex, such as that of the combined references of Griffiths et al. and Yngve to generate a complex useful in the treatment or diagnosis of tumors with minimal side product formation. Microwave acceleration techniques have been utilized

since the 1970's and 1980's in a number of production methods for radioactive precursors and radiotracers labeled with positron-emitting nuclides. The microwave method is mostly associated with shortened reaction times and encompasses the microwave conditions of the instant claims (Lidström et al.). One would have a reasonable expectation of success for preparing a radiotracer via labeling reactions with the improved microwave technique as the microwave technique was known in the art to be less costly and reduce reaction times of organometallic reactions, such as metal-chelate complexes, wherein the microwave heating can be very rapid, producing heat profiles not easily accessible by other heating techniques.

17. At the time of the invention it would have been obvious to one ordinarily skilled in the art to substitute an anion exchanger, such as that of Maier-Borst et al., which does not require a chelating agent (i.e. EDTA) for separation, for the anion exchanger of Griffiths et al. to separate  $^{68}\text{Ga}$  from its parent nuclide. It is known in the prior art to add a chelating agent, such as EDTA to elute  $^{68}\text{Ga}$  from an aluminum oxide exchanger. The disadvantage of forming a  $^{68}\text{Ga}$ -EDTA complex via addition of a chelating agent (i.e. EDTA) to elute  $^{68}\text{Ga}$  from a metal oxide exchanger is that it requires the destruction of the  $^{68}\text{Ga}$ -EDTA complex before further processing to obtain radiopharmaceutical agents which is both time-consuming and expensive (see Maier-Borst et al. p1, lines 10-16).

18. Also, at the time of the invention it would have been obvious that the anion exchange resin comprising quaternary ammonium groups incorporated in the matrix of styrene and divinylbenzene (Maier-Borst et al.) may comprise the bicarbonate counterion as the bicarbonate provides increased stability for several days, even at

higher temperatures and a minimal amount of swelling and thus greater selectivity of the anion exchange resin (Wheaton et al. p1089, resin swelling; Figure 3).

***Response to Arguments***

19. Applicant's arguments filed 10/28/10 have been fully considered but they are not persuasive.
20. Applicant asserts that Bottcher et al. teaches repeatedly that the separation of the metal complexes is by precipitation and/or crystallization. Thus, the teaching of Bottcher et al. is very clear, that the advantages taught therein are linked to precipitation/crystallization of the desired metal complex from the reaction mixture. The "continuous conversion" referred to by the Examiner as an advantage of Bottcher et al. requires precipitation. The method of present claim 1 does not have such a crystallization/precipitation step. Line 2 of claim 1 has the feature "in a suitable solvent" - thus the reaction is carried out in solution. The radioactive gallium complex would not precipitate, since they are required to be in a form suitable for radiopharmaceutical use.
21. The reference of Bottcher et al. was not explicitly used to teach of the reaction solvent system but the use of the microwave technique with the synthetic scheme for the method of producing a <sup>68</sup>Ga-DOTA-oligonucleotide complex, such as that of Yngve and Griffiths et al. for use as a PET tracer as it would have been advantageous since the microwave technique of Bottcher et al. provides the advantage of short reaction times accomplished by producing heat profiles not easily accessible by other heating techniques.

22. Applicant asserts that the person skilled in the art would know that radiopharmaceuticals are never prepared on a kilogramme scale. The Examiner has responded that the present claim does not recite the scale/concentration. Applicants respectfully remind the Examiner that the claim is directed to the person skilled in the art. Revised claim 1 refers to radiopharmaceuticals, and hence the claim must be construed in that context. Applicants respectfully point out that it is not necessary to specify such scale/concentration details, since they are implicit when the term 'radiopharmaceutical' is an essential feature. Thus, revised claim 1 refers to "radiolabelled gallium complex in a form suitable for use in PET/SPECT radiopharmaceutical imaging". The person skilled in the art would know from the use of such a phrase that (i) the kilogramme scale is not suitable for radioactive/radiopharmaceutical preparations; (ii) radiopharmaceuticals are rarely, if ever, isolated in solid form since the concentrations employed are much too low, and solid radiopharmaceuticals would likely suffer from severe radiolysis (i.e. radiolytic instability) problems due to the high level of concentration of radioactive emissions.

23. The reference of Bottcher et al. was not used to teach of the reaction solvent system, amounts/concentrations of the reagents or a kilogramme scale for the synthesis of the metal complexes of the disclosure but was used to teach that microwave irradiation was known at the time of the instant invention for the preparation of metal complex salts for its advantages of being less costly and providing shorter reaction times. Thus, it would have been obvious to one ordinarily skilled in the art to use the microwave technique with the synthetic scheme for the method of producing a  $^{68}\text{Ga}$ -

DOTA-oligonucleotide complex, such as that of Yngve and Griffiths et al. for use as a PET tracer in a radiopharmaceutical preparation for these advantages.

24. Applicant asserts that Lidstrom is now stated in the Office Action mailed 06/28/1010 to be relied on simply for a general teaching on the increasing use of microwave technology in inorganic chemistry and organic synthesis (paragraphs 17 and 22 of the Office Action). Applicants point out that the present Office Action maintains the same objection of that mailed 02/22/2010. The Office Action mailed 02/22/2010 (at paragraph 12) used Lidstrom more specifically, referring to the entry therein on organometallic reactions (Lidstrom p.9267, last entry). Applicants respectfully submit that the Examiner cannot now arbitrarily choose to ignore the previously-cited, specific teaching of Lidstrom on the most closely- related technology in favor of only the more general teaching therein. Suitable reasoning or justification is respectfully requested as to why the person skilled in art would choose to ignore the clear teaching of Lidstrom - otherwise the Examiner's position, according to Applicants point-of-view, represents a clear application of hindsight.

25. The reference of Lidström et al. was always used as a review of microwave technology of the pertinent art at the time of the instant invention as the rejection mailed 2/22/10 recited the following at paragraph 12, "Lidström et al. (*Tetrahedron* **2001**, 57, 9225-9283) discloses that microwave technology has been used since the late 1970s for inorganic chemistry and 1980s for organic synthesis. The shorter reaction times are the main advantage of the microwave technique as microwave heating can be very rapid, producing heat profiles not easily accessible by other heating techniques (p9226,

paragraph 2; p9231, third full paragraph). The microwave technique can provide 100 W (figure 10) and a metal-macrocyclic chelate complex may be generated via the microwave technique (5.11 Organometallic reactions p9267, last entry)."

26. The statement of paragraph 12 above clearly indicates that microwave technology has been used since the late 1970s for inorganic chemistry wherein the advantage of shorter reaction times is the main advantage of the microwave technique as microwave heating can be very rapid, producing heat profiles not easily accessible by other heating techniques. The indication of the last entry on p 9267 was not intended to be representative of all inorganic reactions via microwave and was not intended to teach of reaction conditions. Thus, it was conceded by the Examiner that the reaction of the last entry on p 9267 was done without solvent (solvent-free) and thus was irrelevant.

27. Lidström et al. was further used to teach that the microwave technique can provide 100 W which encompasses the microwave power conditions of the instant claims.

28. Applicant asserts that Lidstrom is a comprehensive review, citing 603 references - yet only one reference to organometallic reactions is cited. That reference (#521; Shaabani) is to a solvent-free, metal template synthesis. Hence, the person skilled in the art reading Lidstrom at the priority date of the present invention could have no motivation to combine Lidstrom and Griffiths/Yngve, since the single organometallic reaction taught by Lidstrom is completely different in nature to that of Griffiths/Yngve. Hence, the only teaching of Lidstrom on organometallic reactions is that relied on

previously by the Examiner. That same teaching is what Lidstrom provided to the person skilled in the art at the priority date of the present invention. Since present claim 1 refers to organometallic chemistry, the Examiner must justify why the person skilled in the art would be motivated to ignore that clear teaching. Applicants stress that Lidstrom provides only one instance of an organometallic metal complexation reaction using microwave had been reported in the literature, and that used solvent-free concentrations.

29. The reference of Lidström et al. is directed toward organic reactions via microwave and not specifically directed to inorganic reaction and thus was not used to teach of a list of organometallic reactions but was used as a general review of microwave technology at the time of the invention and that the microwave technique was well know since the 1970s for inorganic chemistry.

30. In combination with the reference of Bottcher et al., which teaches of organometallic reactions via microwave, it would have been obvious to one ordinarily skilled in the art at the time of the invention to utilize a the microwave technique for the preparation of the <sup>68</sup>Ga-DOTA-oligonucleotide complex, such as that of the combined references of Griffiths et al. and Yngve as the high-energy input allows short reaction time (i.e. a few minutes). Since the microwave technique was known in the art to be less costly and reduce reaction times of organometallic reactions, such as metal-chelate complexes, one would have a reasonable expectation of success for preparing radiotracer via labeling reactions with this improved microwave technique

***Double Patenting***

31. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

32. Claims 1-3,5 and 8-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,2 and 6-14 of copending Application No. 10/522,206. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of producing a radiolabeled gallium complex of the instant claims encompasses the method for producing a  $^{68}\text{Ga}$ -radiolabeled complex of copending Application No. 10/552,206. Both inventions involve reacting a  $^{68}\text{Ga}$  radioisotope with a bifunctional chelating agent comprising a targeting vector (i.e. peptide or oligonucleotide) under microwave conditions. The microwave technique of copending Application No. 10/552,206 encompasses the microwave conditions of the instant claims (not excluding 80-120 W for 20s to 2 min). The inventions also include the same peptide or oligonucleotide targeting moiety that may be bound to the chelating agent for site-directed localization. The generation of the  $^{68}\text{Ga}$  radioisotope of both applications involves eluting the  $^{68}\text{Ga}$  from a  $^{68}\text{Ge}/^{68}\text{Ga}$  titanium dioxide generator followed by purification of the  $^{68}\text{Ga}$  eluate via a strong anion exchanger comprising  $\text{HCO}_3^-$  counterions. Therefore, the resulting radiolabeled gallium complex of the instant claims is obviously generated via the synthesis and isolated and would encompass that radiolabeled gallium complex of the copending application.

33. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

34. Claims 1-3,5,8-13 and 15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3,7-15 of copending Application No. 11/358,681. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of producing a radiolabeled gallium complex of the instant claims encompasses the method for labeling synthesis of radiolabeled gallium complex of copending Application No. 11/358,681. Both inventions involve reacting a  $^{68}\text{Ga}$  radioisotope with a bifunctional chelating agent comprising a peptide using the same microwave conditions. The inventions also include a targeting moiety that may be bound to the chelating agent for site-directed localization. The generation of the  $^{68}\text{Ga}$  radioisotope of both applications involves eluting the  $^{68}\text{Ga}$  from a  $^{68}\text{Ge}/^{68}\text{Ga}$  titanium dioxide generator followed by purification of the  $^{68}\text{Ga}$  eluate via a strong anion exchanger comprising  $\text{HCO}_3^-$  counterions. Therefore, the resulting radiolabeled gallium complex of the instant claims is obviously generated via the synthesis and isolated and would encompass that radiolabeled gallium complex of the copending application.

35. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### ***Response to Arguments***

36. Applicant's arguments filed 10/28/10 have been fully considered but they are not persuasive.

37. Applicant asserts that they will file a suitable terminal disclaimer in the event that the instant application is deemed allowable.

38. No terminal disclaimers have been filed so the rejections are maintained.

***Conclusion***

No claims are allowed at this time.

39. This is a continuation of applicant's earlier Application No. 10/551,234. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art  
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/Melissa Perreira/  
Examiner, Art Unit 1618